

Serial No.: 10/538,813
Examiner: John Pani
Reply to Office Action Mailed August 2, 2007
Page 9 of 15

REMARKS

Reconsideration is requested in view of the above amendments and the following remarks. Claims 1-7 and 19 have been revised. New claims 21-27 have been added. No new matter has been introduced. Claims 1-27 are pending in the application.

Claim 1 has been revised to include "an insertion element movable relative to the housing for sticking the skin" and "the height detector being provided separately from the insertion element and including a tapered face coming into contact with the skin when the skin swells upward." Support for the revisions can be found in, e.g., Fig. 1 and the accompanying text, e.g., page 9, lines 9-15, and page 13, line 27 to page 14, line 16 of the specification, among other places. Particularly, in Fig. 1, a double-headed arrow adjacent to a needle 21 illustrates the insertion element 2 being movable relative to the housing 1. In addition, Fig. 1 and page 13, line 27 to page 14, line 16 illustrate the height detector 5 being provided separately from the insertion element 2 and including a tapered face 50b.

New claim 21 tracks claims 1, 2, 3 and 4 with additional revisions. Further support for claim 21 can be found at page 18, line 24 to page 23, line 18 of the specification, among other places. Support for new claim 22 can be found at page 22, lines 6-9 of the specification, among other places. New claims 23 and 24 track claims 4 and 5 respectively. New claim 25 tracks claim 1 and further includes the height detector comprising an optical sensor or a touch sensor. Further support for claim 25 can be found at page 31, lines 20-21 of the specification, among other places. New claim 26 tracks claims 1, 2 and 4. Further support for claim 26 can be found at page 13, lines 23-26 of the specification, among other places. New claim 27 tracks claims 1, 2 and 12. Further support for claim 27 can be found at page 13, lines 23-26 of the specification, among other places.

Claim Objections

Claims 1, 2, 4, 5, 6 and 19 are objected to due to informalities. Claims 1, 2, 4, 5, 6 and 19 have been editorially revised to address the issues. Withdrawal of the objections is respectfully requested.

Serial No.: 10/538,813
Examiner: John Pani
Reply to Office Action Mailed August 2, 2007
Page 10 of 15

Claim Rejections – 35 USC § 112

Claim 3 is rejected under 35 USC § 112, second paragraph, for indefiniteness. Claim 3 has been editorially revised to address the issue. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 1 and 17 are rejected under 35 USC § 102(b) as being anticipated by Ishibashi (US 5,320,607). Applicants respectfully traverse this rejection.

Claim 1 requires a height detector provided separately from an insertion element, which includes a tapered face coming into contact with the skin when the skin swells upward.

Ishibashi fails to disclose the height detector provided separately from the insertion element as required by claim 1. Nor does Ishibashi disclose that the height detector includes a tapered face coming into contact with the skin when the skin swells upward, as required by claim 1. Instead, Ishibashi merely discusses a piercing means 12 being used for piercing the skin. Ishibashi discusses nothing about a height detector being provided separately from the piercing means, much less the height detector including a tapered face.

For at least these reasons, claim 1 is patentable over Ishibashi. Claim 17 depends from claim 1 and is patentable along with claim 1 and need not be separately distinguished at this time. Applicants are not conceding the relevance of the rejection to the remaining features of the rejected claims.

Claim Rejections – 35 USC § 103

Claims 1-3, 9-11 and 17-20 are rejected under 35 USC 103(a) as being unpatentable over Takinami et al. (WO 02/07599) in view of Wagner (US 4,600,403). Applicants respectfully traverse this rejection.

Claim 1 is directed to a lancing apparatus used for sampling a body fluid out of a skin, which requires a height detector being provided separately from an insertion

Serial No.: 10/538,813
Examiner: John Panl
Reply to Office Action Mailed August 2, 2007
Page 11 of 15

element and including a tapered face coming into contact with the skin when the skin swells upward.

In a conventional lancing apparatus used for sampling a body fluid out of a skin, when a pump is used for generating a negative pressure inside the lancing apparatus to bring an end of the lancing apparatus into contact with a skin, the negative pressure may not be appropriately acting on the skin. For example, if a gap is left between the end of the lancing apparatus and the skin, or, in another case, if the skin is not soft enough for the designed pressure to be applied on the skin, the skin might not swell sufficiently. Thus, when an insertion element is moved forward to insert into the skin, the insertion element may not reach the skin, or may not be inserted deep enough to provoke sufficient bleeding (see page 2, line 16 to page 3, line 5 of the specification and Fig. 18B, among other places). On the other hand, when the skin is soft, a portion of the skin may be taken to press too much against the end of the lancing apparatus, which is referred to as Sk1 in Fig. 18C. This over-pressing on the skin may lead to insufficient bleeding at the piercing spot (see page 3, lines 6-11 of the specification and Fig. 18C, among other places). In the meantime, another portion of the skin, which is referred to as Sk2 in Fig. 18C, may intrude too much into a small hole in the end of the lancing apparatus. In such a case the insertion element is to be inserted too deep into the skin, which will cause not only a considerable damage to the skin, but also significant pain to the patient (see page 3, lines 11-17 of the specification and Fig. 18C, among other places).

The present height detector can detect the height of the skin when a negative pressure is acting upon the skin. It thus helps the user properly insert the insertion element into the skin regardless of the softness of the skin. Moreover, the height detector in claim 1 includes a tapered face coming into contact with the skin when the skin swells upward. This helps the skin generally evenly contact the tapered face when the skin swells upward and thus helps avoid problems caused discussed above at areas of Sk1 and Sk2 as illustrated in Fig. 18C.

The reference disclosures fail to teach or suggest a height detector being provided separately from an insertion element and including a tapered face coming into contact with the skin when the skin swells upward, as required by claim 1. In fact, Wagner is

Serial No.: 10/538,813
Examiner: John Pani
Reply to Office Action Mailed August 2, 2007
Page 12 of 15

directed to an injection apparatus for hypodermic injections. Nowhere does Wagner indicate that the contact rod 112 has a tapered face. Moreover, Wagner does not even suggest the present tapered face because nowhere does Wagner discuss any need for adding a tapered face to the contact rod 112, for example, any problems caused at areas of Sk1 and Sk2 as disclosed in the present application. On the other hand, the Wagner injection apparatus works well when the skin is taken into the end of the injection apparatus and presses the edge of the suction cup 4 (see Wagner, Fig. 20). Therefore, the tapered height detector required by claim 1 is completely distinct from the contact rod 112 for the Wagner injection apparatus. In addition, Takimani et al. are completely silent about the height detector provided separately from an insertion element and including a tapered face coming into contact with the skin when the skin swells upward, as required by claim 1.

For at least this reason, claim 1 is patentable over Takinami et al. in view of Wagner. Claims 2-3, 9-11 and 17-20 ultimately depend from claim 1 and are patentable along with claim 1 and need not be separately distinguished at this time. Applicants are not conceding the relevance of the rejection to the remaining features of the rejected claims.

Claims 4-6 are rejected under 35 USC 103(a) as being unpatentable over Takinami et al. in view of Wagner, and further in view of Golden (US 5,201,560). Applicants respectfully traverse this rejection. Claims 4-6 ultimately depend from claim 1 and are patentable over Takinami et al. in view of Wagner and further in view of Golden for at least the same reasons discussed above regarding claims 1-3, 9-11 and 17-20. Golden does not remedy the deficiencies of Takinami et al. and Wagner. Applicants are not conceding the relevance of the rejection to the remaining features of the rejected claims.

Claims 7-8 are rejected under 35 USC 103(a) as being unpatentable over Takinami et al. in view of Wagner, further in view of Golden, and further in view of Hodges et al. (US 6,612,111). Applicants respectfully traverse this rejection. Claims 7-8

Serial No.: 10/538,813
Examiner: John Pani
Reply to Office Action Mailed August 2, 2007
Page 13 of 15

ultimately depend from claim 1 and are patentable over Takinami et al. in view of Wagner, further in view of Golden, and further in view of Hodges et al. for at least the same reasons discussed above regarding claims 1-3, 9-11 and 17-20. Neither does Golden nor do Hodges et al. remedy the deficiencies of Takinami et al. and Wagner. Applicants are not conceding the relevance of the rejection to the remaining features of the rejected claims.

Claims 12-16 are rejected under 35 USC 103(a) as being unpatentable over Takinami et al. in view of Wagner, further in view of Feingold (US 6,083,236). Applicants respectfully traverse this rejection. Claims 12-16 ultimately depend from claim 1 and are patentable over Takinami et al. in view of Wagner, and further in view of Feingold for at least the same reasons discussed above regarding claims 1-3, 9-11 and 17-20. Feingold does remedy the deficiencies of Takinami et al. and Wagner. Applicants are not conceding the relevance of the rejection to the remaining features of the rejected claims.

New independent claim 21 tracks claims 1, 2, 3 and 4. Original claim 4 is rejected under 35 USC 103(a) as being unpatentable over Takinami et al. in view of Wagner, and further in view of Golden.

Claim 21 requires a controller setting a reference pressure based on a pressure detected by a pressure detector at a time that a height detector has detected that a skin has been raised to a predetermined height. Golden fails to teach or suggest a controller setting a reference pressure based on a pressure detected by the pressure detector as required by claim 21. Instead, Golden merely discusses a predetermined pressure level set by a reference voltage determined in part by potentiometer 106 (see Golden, col. 8, lines 41-45). Nowhere else does Golden indicate how the predetermined pressure is decided. In fact, Golden teaches or suggests nothing about a controller setting a reference pressure based on a pressure detected by a pressure detector, as required by claim 21. None of the other cited references remedies the deficiencies of Golden. Therefore, claim 21 is patentable over the cited references.

Serial No.: 10/538,813
Examiner: John Pani
Reply to Office Action Mailed August 2, 2007
Page 14 of 15

New independent claim 25 requires a height detector comprises an optical sensor or a touch sensor. Nothing in the references disclosures teaches or suggests the invention of claim 25. Therefore, claim 25 is patentable over the cited references.

New independent claim 26 tracks claims 1, 2 and 4. Original claim 4 is rejected under 35 USC 103(a) as being unpatentable over Takinami et al. in view of Wagner, and further in view of Golden.

Claim 26 requires a controller for executing a control so as to maintain a pressure inside the cylindrical portion within a specific range, which is defined by granting a specific tolerance to a reference pressure, which is set at a time that the height detector has detected that the skin has been raised to the predetermined height. As discussed above regarding new claim 21, nothing in the reference disclosures teaches or suggests a reference pressure being set at a time that the height detector has detected that the skin has been raised to the predetermined height. None of the other cited references remedies the deficiencies of Golden. Moreover, Golden is directed to a vacuum cup control apparatus and is in a significantly different field than Takinami et al. and Wagner, which are directed to a body fluid composition measuring apparatus and an injection apparatus for hypodermic injections. Applicants respectfully submit that there is no reasonable basis to combine the three references as the rejection requires to meet claim 26. For at least these reasons, claim 26 is patentable over the cited references.

New independent claim 27 tracks claims 1, 2 and 12. Original claim 12 is rejected under 35 USC 103(a) as being unpatentable over Takinami et al. in view of Wagner, further in view of Feingold.

Feingold is directed to a keratome method and is in a significantly different field than Takinami et al. and Wagner, which are directed to a body fluid composition measuring apparatus and an injection apparatus for hypodermic injections. Applicants respectfully submit that there is no reasonable basis to combine the three references as the

Serial No.: 10/538,813
Examiner: John Pani
Reply to Office Action Mailed August 2, 2007
Page 15 of 15

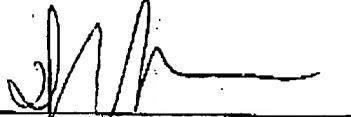
rejection requires to meet claim 27. For at least these reasons, claim 27 is patentable over the cited references.

In view of the above, favorable reconsideration in the form of a notice of allowance is respectfully requested. Any questions regarding this communication can be directed to the undersigned attorney, Douglas P. Mueller, Reg. No. 30,300, at (612) 455-3804.

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER &
LARSON, P.C.
P.O. Box 2902-0902
Minneapolis, MN 55402-0902
(612) 455-3800

Dated: February 4, 2008

By: 

Douglas P. Mueller
Reg. No. 30,300

DPM/cy